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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,464	03/03/2006	Yves Mayeresse	B45326	1405

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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	**PAPER NUMBER**
1648	

NOTIFICATION DATE	DELIVERY MODE
04/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,464	MAYERESSE ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 30, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-32* is/are pending in the application.

4a) Of the above claim(s) *16-19 and 25-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 20-22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-15, 20-22 and 24 are examined on the merits. Claims 16-19 and 25-32 remain withdrawn from consideration since they are drawn to a nonelected invention (see previous Office action).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 30, 2008 was filed after the mailing date of the non-final Office action on July 30, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

Applicant's arguments with respect to claims 1-15, 20-22 and 24 have been considered but are moot in view of the new ground(s) of rejection. However, some previously referenced publications are relied upon in the following rejections and therefore responses to related arguments are addressed below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(New Rejection) Claims 1-3, 6, 8-10, 12-15 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23, 27, 28, 30-35 and 40 of copending Application No. 10/533,462. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of the co-pending application and that of the instant application are obvious variants since each are drawn to compositions containing inactivated polio virus and polysaccharides or oligosaccharides and a stabilizing agent formulated as a dried composition. These compositions are contained in a liquid repellant container.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(New Rejection) Claims 1-3, 6, 8-10 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 34 and 36-41 of copending Application No. 11/587,023. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of the co-pending application and that of the instant application are obvious variants since each are drawn to

compositions containing inactivated polio virus and polysaccharides or oligosaccharides of bacteria and a stabilizing agent formulated as a dried highly viscous liquid. These compositions are contained in a liquid repellant container.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

(New Rejection) Claims 1-15, 20-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boutriau et al. (WO 02/00249 A2), Kurikka et al. (Journal of Pediatrics, 1996), Troung-Le et al. (US 7,135,180 B2) and Volken et al. (US 6,051,238).

The claimed invention is drawn to a vaccine composition of an inactivated polio virus (IPV), a capsular saccharide from *Haemophilus influenzae* b (Hib) and/or *N. meningitides* A, C, Y or W, or a combination thereof, which are conjugated to either a carrier protein (the same type or different proteins) or a tetanus toxoid (TT) and a stabilizing agent. The composition has been dried either by freeze-dried process or as a foamed glass composition and the polysaccharide or oligosaccharide is adsorbed onto aluminum phosphate, which are contained in a water repellent interior. The claimed invention is also drawn to a kit comprising one container with the IPV, Hib and *N. meningitides* saccharides, dried and another container with liquid acellular or whole cell DTP and Hepatitis B surface antigen (HBV-SAg). The composition further contains phenol red. For purposes of examination, the interpretation of a dried composition is guided by the specification which states on page 6, lines 24-30: "A dried solid is a formulation which has had solvent removed by a process of lyophilisation, sublimation, evaporation or desiccation so that less than or equal to 15%, 12%, 10%, 7%, 5%, 4%, preferably 3%, 2% or most preferably 1%

solvent remains." and A highly viscous liquid is defined on page 7, lines 1-2, as "a material with a solvent content less than or equal to 15, 12, 10, preferably 8, 5, 4, 3, 2, or 1%." Therefore, any dried composition can be at the same time a dried, highly viscous liquid.

Boutriau et al. teach a multi-valent vaccine composition comprising IPV of types 1, 2 and 3 (most preferably the Salk polio vaccine), which is the IPV utilized in the instant application, polysaccharides of Hib and *N. meningitides* A, C, Y and W, which can be conjugated to carrier proteins. Or in the case of Hib saccharides, it can be conjugated to TT. Furthermore, Boutriau et al. teach the additional antigens from Diphtheria toxoid and whole cell Pertussis (DTPw) and Hepatitis B antigens can also be considered in the multi-valent vaccine. Boutriau et al. teach a kit comprising the various antigens, which can be placed into two separate vials. One vial could contain DTPw and Hepatitis B, and the other could contain Hib and *N. meningitidis* saccharides. Boutriau et al. also teach the use of aluminum phosphate as an adjuvant in order to complement the administered antigens by adsorption to them and the use of sucrose, a stabilizing agent, when lyophilizing a sample. However, Boutriau et al. do not teach the specific drying of IPV with a stabilizing agent and a bacterial saccharide or the addition of phenol red.

Kurikka et al. focus on vaccination with multiple antigens of Hib, IPV, PRP-D, PRP-T and DTP. In particular, PRP-T contained lyophilized tetanus toxoid conjugated to *Haemophilus influenzae* b polysaccharide. Kurikka et al. also teach the increased immunogenicity to polysaccharides that are coupled to a carrier protein. These vaccines were kept in a glass vial. However, Kurikka et al. do not teach the lyophilization or stabilizing of the vaccines as a foamed glass composition of the combined antigens in a vaccine, in a container with a water repellent inner surface.

Truong-Le, V. is drawn to methods of preserving viruses, bacteria, vaccines, nucleic acids, antibodies, etc. with stabilizing agents such as sucrose, mannitol or sorbitol. The stored compositions can be kept in a freeze-dried (i.e. lyophilized) state in a siliconized glass vial (which provides a water repellent inner surface).

Volken et al. teach the formation of vaccine compositions containing viruses or components thereof. Some virus considered were, polio, chicken pox, etc., as part of a monovalent, or multivalent composition. Volken et al. also teach the addition of phenol red into the vaccine composition in order to monitor the pH. In addition, Volken et al. also teach lyophilization of such compositions in order to stabilize them.

It would have been obvious to one of ordinary skill in the art to modify the compositions taught by Boutriau et al. and Kurikka et al. in order to provide a dried multi-valent vaccine of IPV and bacterial saccharides as a foamed glass composition with a stabilizing agent. One would have been motivated to do so, given the suggestion by Boutriau et al. and Kurikka et al., that the compositions be modified in order to incorporate the various antigens of interest into a stable vaccine composition with sucrose, a stabilizing agent followed by lyophilization and that compositions such as that claimed be utilized in simultaneous vaccinations, respectively. There would have been a reasonable expectation of success, given the knowledge that several methods of freeze drying (lyophilization) vaccine compositions with various stabilizing agents increases the potential shelf life for said vaccine and can be kept in a container with a water repellent inner surface, as taught by Truong-Le, and also given the knowledge that adding phenol red to a vaccine composition containing single or multiple antigens can assist in monitoring the pH of

such a composition, as taught by Volkin et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to arguments:

Applicants argue that Kurikka et al. do not disclose a single immunogenic composition comprising IPV, a bacterial polysaccharide or oligosaccharide and a stabilizing agent, nor does it disclose such a composition formulated as a dried composition. In contrast, Kurikka et al. compare seroresponses to five different vaccination schedules for Haemophilus influenzae type b-tetanus toxoid conjugate. Therefore, IPV was merely administered concurrently with the PRP-T and DTP vaccines, not within the same immunogenic composition. In response, even though Kurikka et al. do not teach combining PRP-T, IPV, Hib and DTP, prior to inoculating a host, their research provides examples of successful (i.e., immuno-responsiveness) administration of multiple antigens from distinct pathogens. In addition, the newly cited Boutriau et al. document teaches combining such antigens into multi-valent compositions.

Applicants argue that Truong-Le does not teach combining IPV with a bacterial polysaccharide or oligosaccharide and a stabilizing agent as a dried composition and that preserving IPV is not suggested either. In response, even though Truong-Le does not teach the specifically claimed invention, the technology taught can be applied to IPV since coronaviruses, which contain the same genome format as IPV, are discussed in Truong-Le.

Claim Objections

Claims 1 and 20 are objected to because of the following informalities: the acronyms for Inactivated Polio Virus (IPV) and Diphtheria, tetanus and *Bordetella pertussis* (DTP) should be also stated in full the first time they appear in the claims. Appropriate correction is required.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/

Examiner
Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648